

Attachment C₂



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

[We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.]

Issued: October 29, 2008

Posted: November 5, 2008

[Name and address redacted]

Re: OIG Advisory Opinion 08-19

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding an Internet advertiser's proposal to extend its "pay per call" or "pay per lead" advertising business to the chiropractic industry (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement constitutes grounds for the imposition of sanctions under the exclusion authority at section 1128(b)(7) of the Social Security Act (the "Act") or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or

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reward referrals were present, but that the Office of Inspector General (“OIG”) will not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement.

This opinion may not be relied on by any persons other [name redacted], the requestor of this opinion, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

[Name redacted] (the “Internet Advertiser”) is not a health care provider or supplier, nor is it affiliated with the health care industry (other than through future performance of services under the Proposed Arrangement). The Internet Advertiser specializes in creating Internet platforms for “pay per call” or “pay per lead” advertising. These Internet platforms direct potential customers seeking services in a particular industry to businesses providing those services located within a designated geographic area. The Internet Advertiser currently operates web sites providing customer leads to businesses in the self-storage, health club, and veterinarian industries. Under the Proposed Arrangement, the Internet Advertiser will expand its business into the chiropractic industry.¹ Some of the potential patients who will visit the Internet Advertiser’s chiropractic industry web site may be seeking services covered in whole or in part by a Federal health care program, including Medicare and Medicaid.

Each chiropractor subscribing to the Internet Advertiser’s services (the “Subscribers”) will enter into an electronic agreement with the Internet Advertiser setting forth the terms of the arrangement. Each Subscriber will be assigned a telephone number and/or email address owned by the Internet Advertiser.² When potential patients visit the chiropractic industry web site, they will be prompted to enter their zip code. The Internet Advertiser will not

¹ The advisory opinion request also indicates that the Internet Advertiser will expand its business into the child care industry, using the same business model as described for the chiropractic industry. In some limited circumstances, child care centers may provide services covered in whole or in part by Federal health care programs, as defined by 42 U.S.C. § 1320a-7b(f), including, for example, Medicaid. Therefore, some potential customers may be directed to the small number of child care centers that provide some services payable, at least in part, by a Federal health care program. To the limited extent this occurs, our analysis of the Proposed Arrangement in the context of the chiropractic industry applies equally in the context of the child care industry.

² The Internet Advertiser will assign its own proprietary telephone numbers and/or email addresses to Subscribers as a means of tracking and billing for the advertising services it provides.

collect, nor will it retain, any health care information, such as payer information, medical history, diagnosis, and the like, from potential patients. Based on the zip code entered, potential patients will receive the assigned phone number and/or email address for each Subscriber located within a specified distance of the zip code area.

The number of Subscriber contacts provided to a potential patient will depend solely on how many Subscribers are located within or near the zip code that the potential patient enters. For some zip codes, there may be multiple Subscribers in the designated geographic location. For others, there may be only one Subscriber or none at all. The chiropractic industry web site will contain a disclaimer notifying potential patients that the web site is a directory where chiropractors pay a fee to be listed. If the potential patient chooses to call or email one or more Subscribers from the list, the Internet Advertiser will re-direct the phone calls or forward the emails to the selected Subscribers.³ The Subscribers then have an opportunity to follow-up with the potential patient.

Each Subscriber will pay the Internet Advertiser on a per-call/per-email basis for each phone call that is routed to the Subscriber that is over thirty seconds in length (as tracked by the Internet Advertiser's system) and for each email that is forwarded.⁴ The Internet Advertiser has certified that the fee per call/per email will represent the fair market value in an arm's-length transaction of the advertising services it provides. The Internet Advertiser has further certified that its compensation under the Proposed Arrangement will not depend in any way on whether the potential patient decides to become a patient of that Subscriber, nor will it depend in any way on the specific chiropractic services utilized, if any. The Internet Advertiser has also certified that its compensation under the Proposed Arrangement will not depend in any respect on whether the potential patients who contact the Subscribers are Federal health care program beneficiaries or obtain Federal health care program services. Each Subscriber will pay the same rate for the Internet Advertiser's services.⁵ The fees will be billed on a monthly basis, and there will be no monthly minimums or long-term commitments required. Subscribers may terminate their agreements with the Internet Advertiser at any time with two business days' notice.

There will be no fee charged by the Internet Advertiser to potential patients who use the web site and/or contact a Subscriber. The Internet Advertiser will not offer potential patients anything of value in connection with using the web site, including, but not limited

³ The Internet Advertiser will record calls from potential patients and save them for up to sixty days, at the Subscriber's option.

⁴ If the potential patient elects to telephone the Subscriber, the telephone call must last thirty seconds in order to be considered a "lead" for billing purposes.

⁵ From time to time, the Internet Advertiser may offer discounts or special promotional fees that will be offered uniformly.

to, discounts on chiropractic services provided by Subscribers or other items or services for free or a reduced price.

II. LEGAL ANALYSIS


A. Law

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible “kickback” transaction. For purposes of the anti-kickback statute, “remuneration” includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of \$25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. § 1001.952(d), is potentially applicable to the Proposed Arrangement. Among the conditions of this safe harbor are that (i) the aggregate compensation to be paid under the contract must be fixed in advance; (ii) the compensation must be consistent with fair market value in an arm’s-length transaction; and (iii) the compensation must not be determined in a manner that takes into




account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made by a Federal health care program. The Proposed Arrangement does not qualify for the protection under this safe harbor because the aggregate compensation under the Proposed Arrangement is not fixed in advance.

The safe harbor for referral services, 42 C.F.R. § 1001.952(f), is also potentially applicable to the Proposed Arrangement. This safe harbor protects referral service payments between an individual or entity (a “participant”) and another entity serving as a referral service (a “referral service”), provided certain conditions described in the regulation are satisfied. Among the conditions to be satisfied under the safe harbor are that payments made by participants to the referral service are assessed equally against, and collected equally from, all participants and are based only on the cost of operating the referral service. Payments may not be based on the volume or value of referrals to or business generated by either party for the other party for which payment may be made by a Federal health care program. In addition, the safe harbor requires that the referral service make specific disclosures to each person seeking a referral. The Proposed Arrangement does not qualify for the protection under this safe harbor because the payments are not based only on the cost of operating the referral service, and the Internet Advertiser will not make the required, specific disclosures to each person seeking a referral.

B. Analysis

While the Proposed Arrangement has characteristics of both an advertising arrangement and a referral service, we analyze the Proposed Arrangement as an advertising arrangement, as it is unlike a typical, non-profit referral service operating for the convenience and support of patients and is not the type of referral service for which the safe harbor at 42 C.F.R. § 1001.952(f) was designed. Moreover, the requestor has characterized the Proposed Arrangement as an advertising arrangement. Advertising activity, like any marketing, is meant to induce the use of an item or service. Where any of the advertised items or services are reimbursable, in whole or in part, by a Federal health care program, the anti-kickback statute is potentially implicated. Per patient, per unit-of-service, or similar variable compensation structures are particularly problematic under the statute, because they relate to the volume or value of business potentially generated between parties.

Here, the Internet Advertiser will be owed compensation on a “per call” or “per lead” basis from Subscribers for an online advertising service that connects the Subscribers with potential patients, some of whom may be Federal health care program beneficiaries. Notwithstanding the general concerns noted above, for a combination of the following reasons, we conclude that the Proposed Arrangement presents a minimal risk of Federal health care program abuse, and therefore we would not seek to impose administrative sanctions under the anti-kickback statute.



First, the Internet Advertiser is not a health care provider or supplier, nor is it affiliated with the health care industry (other than through future performance of services under the Proposed Arrangement). Under the Proposed Arrangement, the Internet Advertiser will utilize an Internet platform to collect zip code information from potential patients. The Internet Advertiser will not collect health care information, such as payer information, medical history, diagnosis, and the like. The Proposed Arrangement is distinguishable in these ways from potentially problematic arrangements involving marketing by health care providers and suppliers. Marketing by health care providers and suppliers (particularly “white coat” marketing by health care professionals such as physicians) is subject to closer scrutiny, since health care providers and suppliers are in a position of trust and may exert undue influence when recommending health-care related items or services, particularly to their own patients.

Second, the advertising under the Proposed Arrangement will not target Federal health care program beneficiaries. The web site will be publically accessible, and use by potential patients will be unrestricted. The web site will not request insurer or other payer information from potential patients. All potential patients utilizing the Internet Advertiser’s services will receive the same automated service. The Internet Advertiser’s compensation under the Proposed Arrangement will not depend in any respect on whether the potential patients who contact the Subscribers are Federal health care program beneficiaries or obtain Federal health care program services.

Third, under the Proposed Arrangement, fees paid by a Subscriber will not depend in any way on whether the potential patient decides to become a patient of that Subscriber, nor will they depend in any way on the specific chiropractic services utilized, if any. All chiropractors who choose to utilize the Internet Advertiser’s services will be charged uniformly for those services. A Subscriber will be billed for the Internet Advertiser’s services when the potential patient uses the contact information from the web site to contact the Subscriber.⁶ This fee structure is distinguishable from problematic “success fees” that tie compensation directly or indirectly to Federally payable business.

Fourth, the Internet Advertiser will not steer patients to particular chiropractors. The Internet platform employed by the Internet Advertiser to connect potential patients with

⁶ The Internet Advertiser has certified that the fee for its advertising services will be consistent with fair market value in an arm’s-length transaction. We are not authorized to opine on whether fair market value shall be, or was, paid or received for any goods, services, or property. See section 1128D(b)(3) of the Act. Therefore, we do not express an opinion about whether the advertising services fee is fair market value. If the fee is not fair market value, this opinion is without force and effect.



Subscribers will serve the limited function of providing a potential patient with contact information for all of the Subscribers located within the potential patient's immediate area. The Internet platform will perform this function solely on the basis of the potential patient's zip code, which he or she will submit on the web site. The web site will contain a disclaimer notifying potential patients that the web site is a directory where the chiropractors listed pay a fee to be listed. Potential patients will pay no remuneration and receive no remuneration (e.g., coupons for discounted chiropractic services provided by Subscribers) for using the Internet Advertiser's web site.

For the foregoing reasons, we conclude that we would not impose administrative sanctions arising in connection with the anti-kickback statute on [name redacted] for the Proposed Arrangement.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement would not generate prohibited remuneration under the anti-kickback statute and, therefore, the Proposed Arrangement would not constitute grounds for the OIG to impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act).

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted], the requestor of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.
- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor of this opinion.
- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.
- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.
- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the requestor with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the requestors with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General

